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22 EDWARDS LIFESCIENCES CORPORATION and
23 EDWARDS LIFESCIENCES LLC
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16 IN THE UNITED STATES DISTRICT COURT
17 FOR THE CENTRAL DISTRICT OF CALIFORNIA
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EDWARDS LIFESCIENCES CORPORATION, a Delaware corporation, and EDWARDS LIFESCIENCES LLC, a Delaware corporation) Case No. 8:19-cv-345
Plaintiff,) FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT
v.) DEMAND FOR JURY TRIAL
ABBOTT CARDIOVASCULAR SYSTEMS, INC., a California corporation, ABBOTT LABORATORIES, INC., a Delaware Corporation, and EVALVE, INC., a Delaware Corporation)
Defendants.)

Plaintiffs Edwards Lifesciences Corporation and Edwards Lifesciences LLC, for their complaint against Defendants Abbott Cardiovascular Systems, Inc., Abbott Laboratories, Inc., and Evalve, Inc. allege as follows:

I. THE PARTIES

1. Plaintiff Edwards Lifesciences Corporation is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Edwards Way, Irvine, California 92614.

2. Plaintiff Edwards Lifesciences LLC is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Edwards Way, Irvine, California 92614.

3. Defendant Abbott Cardiovascular Systems, Inc. is a corporation organized and existing under the laws of the State of California, with its principal place of business at 3200 Lakeside Drive, Santa Clara, California 95054.

4. Defendant Abbott Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

5. Defendant Evalve, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 4045 Campbell Avenue, Menlo Park, California 94025.

6. Edwards Lifesciences Corporation and Edwards Lifesciences LLC shall be collectively referred to herein as “Plaintiffs” or “Edwards Lifesciences.” Abbott Cardiovascular Systems, Inc., Abbott Laboratories, Inc., and Evolve, Inc. shall be referred to herein as “Defendants” or “Abbott.”

II. JURISDICTION AND VENUE

7. This is an action for patent infringement arising under the patent laws of the United States of America, Title 35, United States Code. This Court has original jurisdiction over the subject matter of this action pursuant to 28

¹ U.S.C. §§ 1331 and 1338(a).

2 8. Defendants are engaged in the business of manufacturing, selling,
3 offering for sale, exporting, and/or importing mitral valve repair devices sold
4 under the names MitraClip, MitraClip NT, MitraClip NTR, and MitraClip XTR
5 (collectively, the “Accused Products”) in the United States, including within this
6 District.

7 9. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b),
8 because the Defendants have committed acts of infringement in this District,
9 and because Defendants Abbott Cardiovascular Systems and Abbott
10 Laboratories, Inc. have several established places of business in this district,
11 including in Temecula, California. For purposes of this lawsuit, Evalve, Inc.
12 and Abbott Laboratories, Inc. consent to venue in the Central District of
13 California.

14 10. This Court has personal jurisdiction over Defendants. The
15 Defendants have committed acts of infringement in this District, including
16 manufacturing, selling, offering for sale, exporting, and/or importing the
17 Accused Products in this District.

III. THE PATENTS-IN-SUIT

19 11. On April 13, 2004, the United States Patent and Trademark Office
20 issued United States Patent No. 6,719,767 (“the ’767 Patent”) entitled “Device
21 and a Method for Treatment of Atrioventricular Regurgitation,” a true and
22 correct copy of which is attached as Exhibit 1.

23 12. Edwards Lifesciences Corporation is the assignee of all rights to
24 the '767 Patent, including the right to sue for and recover all past and present
25 damages for infringement of the '767 Patent. Edwards Lifesciences LLC is the
26 exclusive licensee of the '767 Patent.

27 13. On March 14, 2006, the United States Patent and Trademark Office
28 issued United States Patent No. 7,011,669 ("the '669 Patent") entitled "Device

1 and a Method for Treatment of Atrioventricular Regurgitation,” a true and
2 correct copy of which is attached as Exhibit 2.

3 14. Edwards Lifesciences Corporation is the assignee of all rights to
4 the ’669 Patent, including the right to sue for and recover all past and present
5 damages for infringement of the ’669 Patent. Edwards Lifesciences LLC is the
6 exclusive licensee of the ’669 Patent.

7 15. On November 22, 2011, the United States Patent and Trademark
8 Office issued United States Patent No. 8,062,313 (“the ’313 Patent”) entitled
9 “Device and a Method for Treatment of Atrioventricular Regurgitation,” a true
10 and correct copy of which is attached as Exhibit 3.

11 16. Edwards Lifesciences Corporation is the assignee of all rights to
12 the ’313 Patent, including the right to sue for and recover all past and present
13 damages for infringement of the ’313 Patent. Edwards Lifesciences LLC is the
14 exclusive licensee of the ’313 Patent.

15 17. The ’767 Patent, the ’669 Patent, and the ’313 Patent are
16 collectively referred to herein as the Asserted Patents.

17 **IV. COUNT 1 – INFRINGEMENT OF THE ’767 PATENT**

18 18. Edwards Lifesciences incorporates paragraphs 1 through 17 as
19 though fully set forth herein.

20 19. Defendants have made, used, sold, and/or offered for sale the
21 Accused Products in the United States, imported the Accused Products into the
22 United States, and/or exported from the United States all or a substantial portion
23 of the components of the Accused Products for which no substantial
24 noninfringing use exists, including within this District.

25 20. Defendants have directly infringed at least Claim 14 of the ’767
26 Patent either literally or under the doctrine of equivalents by manufacturing,
27 selling, offering for sale, and/or importing the Accused Products, in violation of
28 35 U.S.C. § 271(a).

1 21. By way of example, and not limitation, Defendants' direct
2 infringement of Claim 14 of the '767 Patent is shown in the claim chart in
3 Exhibit 4, attached hereto and incorporated herein by reference, which compares
4 exemplary Claim 14 to the Accused Products.

5 22. Each version of the MitraClip implant requires a clip delivery
6 system, including a catheter, for implantation. The clip delivery system is
7 especially made for use with the MitraClip. The MitraClip Instructions for Use
8 instruct clinicians to use the clip delivery system to implant the MitraClip.

9 23. One or more Defendants have also infringed at least Claim 14 of
10 the '767 Patent by supplying or causing to be supplied from the United States all
11 or a substantial portion of the components of the Accused Products, including
12 the MitraClip implant and/or the clip delivery system, in such a manner as to
13 actively induce the combination of the components outside the United States in
14 a manner that would infringe if the combination occurred within the United
15 States, in violation of 35 U.S.C. § 271(f)(1).

16 24. One or more Defendants have also infringed at least Claim 14 of
17 the '767 Patent by supplying components of the Accused Products, including
18 the MitraClip and/or the clip delivery system, that are especially made or
19 adapted for use in the Accused Products and are not a staple article or
20 commodity of commerce suitable for substantial noninfringing use, with
21 knowledge that the components are so made or adapted and intending that the
22 components will be combined outside the United States in a manner that would
23 infringe the patent if such combination occurred within the United States, in
24 violation of 35 U.S.C. § 271(f)(2).

25 25. Defendants had actual knowledge of the '767 Patent prior to the
26 filing of this Complaint. For example, on September 22, 2004 during the
27 prosecution of U.S. Patent No. 7,335,213, Defendant Abbott Cardiovascular
28 Systems cited the '767 Patent in an information disclosure statement to the

1 United States Patent and Trademark Office. As an additional example, on
2 January 30, 2010, during the prosecution of U.S. Patent No. 7,736,388,
3 Defendant Evalve, Inc. cited the '767 Patent in an information disclosure
4 statement to the United States Patent and Trademark Office. Abbott
5 Laboratories, Inc. had actual knowledge of the '767 Patent at least as early as
6 February 22, 2019, when Edwards filed their Complaint in this case.

7 26. Edwards Lifesciences has been damaged by Defendants' infringing
8 activities in an amount to be determined at trial, but in no event less than a
9 reasonable royalty.

10 **V. COUNT 2 – INFRINGEMENT OF THE '669 PATENT**

11 27. Edwards Lifesciences incorporates paragraphs 1 through 26 as
12 though fully set forth herein.

13 28. Defendants have induced infringement of the '669 Patent under 35
14 U.S.C. § 271(b), by, for example, instructing clinicians to use the Accused
15 Products in a manner that constitutes direct infringement of the '669 Patent.

16 29. Defendants have also contributed to the infringement of the '669
17 Patent under 35 U.S.C. § 271(c) by, for example, offering for sale, selling,
18 and/or importing the Accused Products for use in practicing the patented process
19 of the '669 Patent, where the Accused Products constitute a material part of the
20 invention, and are not a staple article or commodity of commerce suitable for
21 substantial non-infringing use, and are known by Defendants to be especially
22 adapted for use in an infringement of the '669 Patent. As a result, the Accused
23 Products have been used by customers and clinicians in a manner that directly
24 infringes at least claim 1 of the '669 Patent.

25 30. For example, in the MitraClip Instructions For Use (attached hereto
26 as Exhibit 5), Defendants instruct clinicians to use the Accused Products in a
27 manner that infringes, either literally or under the doctrine of equivalents, one or
28 more claims of the '669 Patent, including at least Claim 1.

1 31. When clinicians perform the method of using the Accused
2 Products, as described at least in Exhibit 5, they are directly infringing at least
3 Claim 1 of the '669 Patent as described in the claim chart in Exhibit 6, attached
4 hereto and incorporated herein by reference.

5 32. Defendants knew that clinicians would infringe the '669 Patent by
6 using the Accused Products during the term of the '669 Patent. For example,
7 Defendants provide Instructions for Use (Exhibit 5) to clinicians with the
8 Accused Products. The Instructions for Use instruct the clinician to perform a
9 method of using the Accused Products that would constitute direct infringement
10 of at least Claim 1 of the '669 Patent. Defendants also knew that the Accused
11 Products were not a staple article or commodity of commerce for substantial
12 non-infringing use.

13 33. Defendants had the specific intent to induce and did induce
14 clinicians to infringe the '669 Patent under 35 U.S.C. § 271(b), by, for example,
15 causing clinicians to use the Accused Products in a manner that constitutes
16 direct infringement of at least Claim 1 of the '669 Patent during the term of the
17 '669 Patent, including by providing marketing materials and instructions for
18 use, such as for example the Instructions for Use (Exhibit 5), to clinicians that
19 instruct the clinicians to perform a method of using the Accused Products that
20 infringes at least Claim 1 of the '669 Patent.

21 34. Defendants had actual knowledge of the '669 Patent prior to the
22 filing of this Complaint. For example, on July 25, 2018 during the prosecution
23 of U.S. Patent No. 10,188,392, Defendant Abbott Cardiovascular Systems cited
24 the '669 Patent in an information disclosure statement to the United States
25 Patent and Trademark Office. As an additional example, on April 17, 2007,
26 during the prosecution of U.S. Patent No. 7,736,388, Defendant Eevalve, Inc.
27 cited the '669 Patent in an information disclosure statement to the United States
28 Patent and Trademark Office. Abbott Laboratories, Inc. had actual knowledge

1 of the '669 Patent at least as early as February 22, 2019, when Edwards filed
2 their Complaint in this case.

3 35. Edwards Lifesciences has been damaged by Defendants' infringing
4 activities in an amount to be determined at trial, but in no event less than a
5 reasonable royalty.

6 **VI. COUNT 3 – INFRINGEMENT OF THE '313 PATENT**

7 36. Edwards Lifesciences incorporates paragraphs 1 through 35 as
8 though fully set forth herein.

9 37. Defendants have made, used, sold, and/or offered for sale the
10 Accused Products in the United States, imported the Accused Products into the
11 United States, and/or exported from the United States all or a substantial portion
12 of the components of the Accused Products for which no substantial
13 noninfringing use exists, including within this District.

14 38. Defendants have directly infringed at least Claim 1 of the '313
15 Patent either literally or under the doctrine of equivalents by manufacturing,
16 selling, offering for sale, and/or importing the Accused Products, in violation of
17 35 U.S.C. § 271(a).

18 39. By way of example, and not limitation, Defendants' direct
19 infringement of Claim 1 of the '313 Patent is shown in the claim chart in
20 Exhibit 7, attached hereto and incorporated herein by reference, which compares
21 exemplary Claim 1 to the Accused Products.

22 40. Each version of the MitraClip implant requires a clip delivery
23 system, including a catheter, for implantation. The clip delivery system is
24 especially made for use with the MitraClip. The MitraClip Instructions for Use
25 instruct clinicians to use the clip delivery system to implant the MitraClip.

26 41. One or more Defendants have also infringed at least Claim 1 of the
27 '313 Patent by supplying or causing to be supplied from the United States all or
28 a substantial portion of the components of the Accused Products, including the

1 MitraClip implant and/or the clip delivery system, in such a manner as to
2 actively induce the combination of the components outside the United States in
3 a manner that would infringe if the combination occurred within the United
4 States, in violation of 35 U.S.C. § 271(f)(1).

5 42. One or more Defendants have also infringed at least Claim 1 of the
6 '313 Patent by supplying components of the Accused Products, including the
7 MitraClip and/or the clip delivery system, that are especially made or adapted
8 for use in the Accused Products and are not a staple article or commodity of
9 commerce suitable for substantial noninfringing use, with knowledge that the
10 components are so made or adapted and intending that the components will be
11 combined outside the United States in a manner that would infringe the patent if
12 such combination occurred within the United States, in violation of 35 U.S.C. §
13 271(f)(2).

14 43. Defendants had actual knowledge of the patent application that
15 issued as the '313 Patent prior to the filing of this Complaint. For example, on
16 July 25, 2018, during the prosecution of U.S. Patent No. 10,188,392, Defendant
17 Abbott Cardiovascular Systems cited the patent application that issued as the
18 '313 Patent in an information disclosure statement to the United States Patent
19 and Trademark Office. As an additional example, on January 31, 2010 during
20 the prosecution of U.S. Patent No. 8,052,592, Defendant Evalve, Inc. cited the
21 patent application that issued as the '313 Patent in an information disclosure
22 statement to the United States Patent and Trademark Office. Defendants had
23 actual knowledge of the '313 Patent prior to the filing of this Complaint.
24 Defendants are sophisticated companies that monitor the patents of its
25 competitors and as a result of this monitoring learned that the '313 Patent issued
26 from the patent application. Abbott Laboratories, Inc. had actual knowledge of
27 the '313 Patent at least as early as February 22, 2019, when Edwards filed their
28 Complaint in this case.

1 44. Edwards Lifesciences has been damaged by Defendants' infringing
2 activities in an amount to be determined at trial, but in no event less than a
3 reasonable royalty.

VII. PRAYER FOR RELIEF

5 WHEREFORE, Edwards Lifesciences requests the following relief:

6 45. A judgment in favor of Edwards Lifesciences that Defendants have
7 infringed one or more claims of the '767 Patent;

8 46. A judgment in favor of Edwards Lifesciences that Defendants have
9 induced others to infringe one or more claims of the '669 Patent;

10 47. A judgment in favor of Edwards Lifesciences that Defendants have
11 contributed to the infringement by others of one or more claims of the '669
12 Patent;

13 48. A judgment in favor of Edwards Lifesciences that Defendants have
14 infringed one or more claims of the '313 Patent;

15 49. A judgment in favor of Edwards Lifesciences that this case is
16 exceptional under 35 U.S.C. § 285 and awarding Edwards Lifesciences its
17 attorneys' fees;

18 50. A judgment and order requiring Defendants to pay Edwards
19 Lifesciences damages adequate to compensate for infringement under 35 U.S.C.
20 § 284, which damages in no event shall be less than a reasonable royalty for the
21 use made of the inventions of the Asserted Patents, including supplemental
22 damages for any continuing post-verdict infringement up until the entry of
23 judgment, with an accounting, as needed, pre- and post-judgment interest and
24 costs, including expenses and disbursements;

25 51. A judgment in favor of Edwards Lifesciences, and against
26 Defendants, that interest, costs, and expenses be awarded in favor of Edwards
27 Lifesciences; and

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1 52. Any and all such further necessary relief as the Court may deem
2 just and proper.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: November 7, 2019 By: /s/ Hans L. Mayer

John B. Sganga, Jr.
Craig S. Summers
Christy G. Lea
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Douglas B. Wentz

Attorneys for Plaintiffs,
EDWARDS LIFESCIENCES CORPORATION
and EDWARDS LIFESCIENCES LLC

1 **VIII. DEMAND FOR TRIAL BY JURY**

2 Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs
3 Edwards Lifesciences Corporation and Edwards Lifesciences LLC hereby
4 demand a trial by jury on all issues so triable.

5 Respectfully submitted,
6 KNOBBE, MARTENS, OLSON & BEAR, LLP

7

8 Dated: November 7, 2019 By: /s/ Hans L. Mayer

9 John B. Sganga, Jr.
10 Craig S. Summers
11 Christy G. Lea
12 Joshua J. Stowell
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14 Attorneys for Plaintiff,
15 EDWARDS LIFESCIENCES CORPORATION
16 and EDWARDS LIFESCIENCES LLC

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